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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,414	07/30/2003	Zheng Z. Wu	54334US019	9005
32692	7590	05/27/2008	EXAMINER	
3M INNOVATIVE PROPERTIES COMPANY PO BOX 33427 ST. PAUL, MN 55133-3427				HAGHIGHATIAN, MINA
ART UNIT		PAPER NUMBER		
1616				
NOTIFICATION DATE		DELIVERY MODE		
05/27/2008		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/630,414	WU ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	MINA HAGHIGHATIAN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 18 March 2008.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 29-37 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 29-37 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application
Paper No(s)/Mail Date <u>09/20/07</u> .	6) <input type="checkbox"/> Other: _____ .

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/18/08 has been entered.

Receipt is acknowledged of the Amendments and Remarks filed on 03/18/08 and an IDS filed on 09/20/07. Claim 29 has been amended. No claims have been cancelled or newly added. Accordingly, claims **29-37** remain pending.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claims 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tzou et al (5,776,433) in view of Saidi et al (6,241,969).**

Tzou et al teach pharmaceutical aerosol formulations comprising flunisolide, ethanol and a propellant selected from the group consisting of 1,1,1,2-tetrafluoroethane, 1,1,1,2,3,3-heptafluoropropane, and a mixture thereof (see abstract). The said formulations are in **solution** form and comprise an effective amount of flunisolide, a propellant and **ethanol** in an amount effective to solubilize the flunisolide in the formulation (see col. 1, line 52 to col. 2, line 4). The formulations are filled in an aerosol canister equipped with conventional valves, preferably metered dose valves (see col. 3, lines 40-48). It is further disclosed that “certain containers enhance the chemical stability of certain formulations of the invention and/or minimize the absorption of flunisolide onto the container walls; therefore, it is preferred to contain a formulation of the invention within a **glass aerosol vial** or an **aluminum aerosol vial having an interior formulation chamber coated with a resin that is inert** to flunisolide and preferably does not absorb flunisolide from the formulation. Suitable resins for coating

the formulation chamber include materials commonly employed as interior can coatings, such as epoxy resins (e.g. **epoxy-phenolic resins** and epoxy-urea-formaldehyde resins)" (see col. 4, lines 1-14). Tzou et al lacks specific disclosure on other corticosteroids such as dexamethasone, betamethasone, etc.

Saidi et al teach compositions containing corticosteroids in a **dissolved** state for pulmonary or nasal delivery. The said corticosteroids include dexamethasone, betamethasone, flunisolide, **triamcinolone acetonide**, beclometasone, etc. Particularly preferred are dexamethasone, betamethasone, flunisolide, etc (see abstract and col. 6, lines 8-30). The formulation contains co-solvents such as **ethanol** and propylene glycol (see col. 8, lines 1-10).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the general teachings of Tzou et al on solution formulations containing active agents such as flunisolide (a corticosteroid), propellants and ethanol for inhalation stored in and delivered by a metered dose inhaler having a coated aluminum interior to have looked in the art for other suitable active agents such as dexamethasone, betamethasone as taught by Saidi et al with the reasonable expectation of successfully preparing a formulation that is stable, effective and easy to administer. In other words, **all the claimed elements** were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and **the combination would have yielded predictable results** to one of ordinary skill in the art at the time of the invention.

Furthermore, the claim would have been obvious because the **substitution of one known element for another** would have yielded predictable results to one of ordinary skill in the art at the time of invention.

**Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tzou et al (5,776,433) in view of Saidi et al (6,241,969) as applied to claims 29-36 above and further in view of Randall (3,923,484).**

The combination of references applied above, Tzou et al in view of Saidi et al, lack specific disclosure on fused silica glass.

Randall et al teach a method of producing a glass body composed of two or more oxides (see abstract). The said method involves doping a fused oxide glass, such as **fused silica glass** produced by flame hydrolysis, with a second oxide (see col. 2, lines 39-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teachings of Tzou et al on solution formulations containing active agents such as flunisolide (a corticosteroid), propellants and ethanol for inhalation stored in and delivered by a metered dose inhaler having a glass vial or coated aluminum interior and the teachings of Saidi et al on other corticosteroids such as dexamethasone, betamethasone with the glass body of Randall et al with a reasonable expectation of successfully preparing a formulation that is stable,

and stored in a suitable container. In other words, **all the claimed elements** were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and **the combination would have yielded predictable results** to one of ordinary skill in the art at the time of the invention.

**Claims 29-31 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porush et al (2,868,691) in view of Ashurst et al (6,143,277).**

Porush et al teach a self-propelling composition for inhalation therapy containing a salt of isoproterenol or epinephrine. The said compositions comprise a **medicament dissolved** in a non-toxic liquid propellant in the nature of fluorinated or fluorochlorinated lower aliphatic hydrocarbon, preferably with the aid of a **co-solvent** for both the medicament and the propellant (col. 1, lines 62-72). A suitable co-solvent is **ethanol** (see paragraph bridging columns 2 and 3). The medicament employed in the said composition is one which is therapeutically effective when administered by inhalation and which may be brought into **stable solution**. Such medicaments include **steroids** (col. 2, lines 41-60). Porush lacks disclosure on specific device, active agent, or propellants as claimed.

Ashurst et al teaches a metered dose inhaler having part or all of its internal metallic surfaces coated with one or more fluorocarbon polymers in combination with

one or more non-fluorocarbon polymers, for dispensing an inhalation drug formulation (see abstract). Preferred drug formulations contain salmeterol in combination with an anti-inflammatory steroid such as flunisolide, beclomethasone, budesonide, triamcinolone acetonide, etc (see col. 3, lines 15-30). A polar co-solvent such as **ethanol**, isopropanol and propylene glycol may be added (col. 3, lines 6-12).

Ashurst's compositions contain propellants and suitable propellants include HFA 134a and HFA 227 (see col. 3, lines 55-67). The MDI cans and caps are made of aluminum, an alloy of aluminum, stainless steel or they may be fabricated from **glass** or plastic. The internal surface of the inhaler can be **coated** by a fluorocarbon polymer such as perfluoroalkoxyalkylene (see col. 4, line 47 to col. 5, line 25). It is also disclosed that MDI cans may be coated by the means known in the art of metal coating such as spray-coating (see paragraph bridging col. 5 and col. 6).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the general teachings of Porush et al on solution formulations containing steroids for inhalation to have looked in the art for specific active agents, propellants and device as taught by Ashurst et al with the reasonable expectation of successfully preparing a formulation that is stable, effective and easy to administer. In other words, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

**Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Porush et al (2,868,691) in view of Ashurst et al (6,143,277) as applied to claims 29-31 and 34-36 above and further in view of Ercoli et al (3,755,302).**

The combined references of porush et al and Ashurst et al, discussed above, lack disclosure on specific corticosteroids of claims 32 and 33.

Ercoli et al teach process for the production of 17-monoesters of 17 $\alpha$ , 21-dihydroxy-20-ketosteroids (see abstract). Such ketosteroids include dexamethasone and betamethasone 17-valerate (see Table 1 and Examples).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the solution formulations of the combined references to have looked in the art for other suitable steroids because preparing more stable solution formulations for aerosol delivery with other active agents would provide patients and health care providers with more options and better therapeutic outcomes. In other words, the claim would have been obvious because **the substitution of one known element for another would have yielded predictable results** to one of ordinary skill in the art at the time of the invention.

**Claims 29-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blondino et al (6,290,930) in view of Ashurst et al (6,143,277) and in view of Ercoli et al (3,755,302).**

Blondino et al discloses a **stabilized medicinal aerosol solution** formulations adapted for use in a pressurized aerosol container. The aerosol formulation is formulated from a composition containing **budesonide**, at least one fluoroalkane propellant and a co-solvent (see abstract). It is disclosed that the solution aerosol compositions are filled in a plastic coated glass bottle or an aluminum canister (see col. 4, lines 15-27). The preferred propellants include HFA 134 and HFA 227 or a mixture thereof (col. 3, lines 12-24). Blondino et al lack specific disclosure on other suitable 20-ketosteroid drugs other than budesonide and coated metal canisters.

Ashurst et al, discussed above, teaches a metered dose inhaler having part or all of its internal metallic surfaces coated with one or more fluorocarbon polymers in combination with one or more non-fluorocarbon polymers, for dispensing an inhalation drug formulation. Preferred drug formulations contain salmeterol in combination with an anti-inflammatory steroid. A polar co-solvent such as **ethanol**, isopropanol and propylene glycol may be added. The MDI cans and caps are made of aluminum, an alloy of aluminum, stainless steel or they may be fabricated from **glass** or plastic.

Ercoli et al teach process for the production of 17-monoesters of 17 $\alpha$ , 21-dihydroxy-20-ketosteroids (see abstract). Such ketosteroids include dexamethasone and betamethasone (see Table 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the solution formulations of Blondino et al to have looked in the art for other suitable steroids and other forms of internal coating for the canisters because preparing more stable solution formulations for aerosol delivery with other active agents would provide patients and health care providers with more options and better therapeutic outcomes. Also one would be motivated to employ coated canisters for improved stability of the formulation. In other words, **all the claimed elements** were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have **yielded predictable results** to one of ordinary skill in the art at the time of the invention.

**Claims 29-31 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashurst et al (6,131,566) in view of Saidi et al (6,241,969).**

Ashurst et al teaches a metered dose inhaler having part or all of its internal metallic surfaces coated with one or more fluorocarbon polymers in combination with one or more non-fluorocarbon polymers, for dispensing an inhalation drug formulation

(see abstract). Preferred drug formulations contain salmeterol in combination with an anti-inflammatory steroid such as fluticasone, beclomethasone, budesonide, triamcinolone acetonide, etc (see col. 3, lines 15-30).

Ashurst's compositions contain propellants and suitable propellants include HFA 134a and HFA 227 (see col. 3, lines 55-67). The MDI cans and caps are made of aluminum, an alloy of aluminum, stainless steel or they may be fabricated from **glass** or **plastic**. The internal surface of the inhaler can be **coated** by a fluorocarbon polymer (see col. 4, line 47 to col. 5, line 25). It is also disclosed that MDI cans may be coated by the means known in the art of metal coating such as spray-coating (see paragraph bridging col. 5 and col. 6). Ashurst et al's formulations are in suspension form and lacks specific disclosure on solutions.

Saidi et al teach compositions containing corticosteroids in a dissolved state in the composition. The said corticosteroids include betamethasone, budesonide, triamcinolone, dexamethasone, dexamethasone 21-isonicotinate (see abstract and col. 6, lines 8-30).

It would have been obvious to one of ordinary skill in the art at the time the invention was made given the general teachings of Ashurst et al on formulations containing active agents such as corticosteroids for inhalation stored in and delivered by a metered dose inhaler having a non-metal interior to have looked in the art for other dosage forms of the formulation such as solutions as taught by Saidi et al with the

reasonable expectation of successfully preparing a formulation that is stable, effective and easy to administer. In other words, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

**Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ashurst et al (6,131,566) in view of Saidi et al (6,241,969) as applied to claims 29-31 and 34-36 above and further in view of Randall et al (3,923,484)**

The combination of Ashurst et al and Saidi et al, discussed above, lacks specific disclosure on the fused silica glass of claim 37.

Randall et al, discussed above, teach a method of producing a glass body composed of two or more oxides (see abstract). The said method involves doping a fused oxide glass, such as **fused silica glass** produced by flame hydrolysis, with a second oxide (see col. 2, lines 39-50).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the references because the design incentives or market forces provided a reason to make an adaptation, and the invention resulted from application of the prior knowledge in a predictable manner.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **29-36** are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 6-17 of U.S. Patent No. 6,610,273 in view of Tzou et al (5,776,433). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims in view of Tzou et al. Specifically, the reference claims are drawn to a method of reducing the chemical degradation of a medicinal 20-ketosteroid dissolved in an aerosol formulation or a process for making a chemically stable steroid solution aerosol product. The said formulations comprise a metered dose inhaler product comprising a 20-ketosteroid drug and one or two HFA propellants in a metal container that has a non-metal interior coating. The instant claims are drawn to a pressurized metered dose inhaler containing a solution of an active agent (such as a 20-ketosteroid) an HFA propellant, wherein the container is metal with a non-metal interior surface. The instant claims are silent with regard to a method of

reducing chemical degradation. Tzou et al teach solution formulations of a corticosteroid, flunisolide with ethanol and propellant. It is disclosed that "It has been found that certain containers enhance the chemical stability of certain formulations of the invention and/or minimize the absorption of flunisolide onto the container walls, therefore, it is preferred to contain a formulation of the invention within a glass aerosol vial or an aluminum aerosol vial having an interior chamber coated with resin that is inert". Thus it would have been obvious to one of ordinary skill in the art to have combined the reference claims with teachings of Tzou et al on enhanced stability with reasonable expectation of success.

Claims **29-37** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 29-37 of copending Application No. 11/061,529 (US 20050220717). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims would have been obvious over the reference claims. Specifically, the reference claims are drawn to a medicinal aerosol solution metered dose inhaler product comprising a 20-ketosteroid drug and one or two HFA propellants in a container that has an anon-metal interior surface. The instant claims are drawn to a pressurized metered dose inhaler containing a solution of an active agent (such as a 20-ketosteroid) an HFA propellant, having part or all of its internal surface consisting of a stainless steel, aluminum or coated with an inert coating. Although the instant claims are of a slightly broader scope, they are obvious over the reference claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

Applicant's arguments filed 03/18/08 have been fully considered but they are not persuasive.

With regard to the rejection of claims 29-31 under 103(a) over Ashurst in view of Saidi, Applicant argues that Ashurst is directed to aerosol suspension compositions and not to solutions as claimed. Applicant also argues that Ashurst discloses formulations comprising albuterol and not corticosteroids. This is not persuasive. Applicant is attacking references individually, while the claims have been rejected over a combination of two references and under rules of obviousness. Ashurst teaches formulations (in suspension form) for aerosol delivery comprising salmeterol (albuterol) in combination with corticosteroids. Ashurst also teaches advantages of inner coating of the canister. Saidi teaches solution formulations of corticosteroids for inhalation to pulmonary subsystem. Applicant has not shown that the combination of the references would not have been obvious to a person of ordinary skill in the art at the time of the invention. All the claimed elements have been disclosed by the prior art for use in the same manner as claimed. Thus it would have been obvious to one of ordinary skill in the art to have prepared solutions as supposed to suspensions of corticosteroids and to

Applicant also argues that "the concern for Ashurst et al appears to be albuterol adhering to the inner surfaces of the can, valves and caps of metered dose inhalers".

Applicant then concludes that “the coating was provided to specifically prevent albuterol from sticking to the surface of the MDIs, NOT to increase stability of albuterol”. This is not persuasive. To meet obviousness, prior art does not need to recognize or resolve the same problem as claimed. In *KSR International CO. v. Teleflex Inc.* 82 USPQ 2d 1385 (Supreme Court 2007), Court ruled that, obviousness can come from the references or from the knowledge of a person having ordinary skill in the art. In fact, the Supreme Court stated that the Federal Circuit had erred in four ways, one of which is “by holding that courts and patent examiners should look only to the problem the patentee was trying to solve” and second is “by assuming that a person of ordinary skill attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem”. See KSR, 82 USPQ2d at 1397.

Applicant argues that Saidi does not make up for the deficiencies of Ashurst because Saidi provides solution formulations of corticosteroids for use in nebulizers, not in MDIs. This is again not persuasive. While Saidi does concentrate on nebulization as a preferred device for administration of the solution formulations, MDIs have been disclosed for administration of solution formulations. In column 1, line 41 to line 43, it is clearly disclosed that “In an MDI, the drug may be suspended or solubilized in a non-aqueous propellant”. Furthermore, Saidi was relied upon for its teaching of solution formulations of corticosteroids and not the device. Ashurst discloses the device.

Applicant also argues that “Saidi et al did NOT test these solution compositions in MDIs. And, as noted above, Ashurst et al did not test any solution formulation in MDIs and did not test any drug other than albuterol”. This is not persuasive. It is not

necessary for every prior art to have tested every element in order to render the claims obvious. There is no reason to believe, and Applicant has not shown any reason that the solution formulation of corticosteroids can not be administered by a metered dose inhaler. Furthermore, at the very least, the claims would have been obvious because a person of ordinary skill has **good reasons** to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and **common sense**.

With regard to the Double Patenting rejection of claims over co-pending Application No. 11/061,529, Applicant stated that "Applicants enclose a terminal disclaimer that disclaims the terminal part .....". However, there is no terminal disclaimer filed, therefore the rejection remains pending.

**No claim is allowable.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINA HAGHIGHATIAN whose telephone number is (571)272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mina Haghigatian/

Mina Haghigatian  
Primary Examiner  
Art Unit 1616